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(271/054)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

N. Parker Willis, et al.

Serial No.: 09/128,304

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For: **A DYNAMICALLY ALTERABLE
THREE-DIMENSIONAL
GRAPHICAL MODEL OF A
BODY REGION**

Confirmation No.: 2536

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Examiner: Bleni M. Mantis Mercader

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OCT 21 2004**PROPOSED CLAIMS (DO NOT ENTER)**

1. (Currently Amended) A method of generating a three-dimensional graphical model of a region located within a living body, comprising the steps of:

- (a) generating a three-dimensional model of a region of interest;
- (b) determining the three-dimensional location of a physical characteristic in the region of interest using at least one probe positioned within the living body;
- (c) deforming performing a transformation on the model to at least approximately incorporate the physical characteristic at the determined three-dimensional location; and
- (d) displaying the model on a graphical display.

2. (Currently Amended) The method of claim 1 further including:

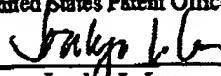
sequentially performing transformations on the model by repeating steps (b) through (d)
multiple times for different probe locations to increase the conformity of the model to the actual region of interest within the living body.

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3. (Original) The method of claim 1 further including the step of
- (e) determining the relative three-dimensional location of a medical device positioned in the region of interest in the living body and graphically representing the medical device superimposed on the model at the determined three-dimensional location.
4. (Original) The method of claim 3 wherein the medical device is the at least one probe.
5. (Original) The method of claim 3 wherein:
- the medical device includes at least one mapping electrode;
- step (e) includes determining the relative three-dimensional location of the at least one mapping electrode; and
- the method further includes the steps of:
- (f) detecting electrical activity using the at least one mapping electrode; and
- (g) generating a map of the detected electrical activity and superimposing the map on the model at a three-dimensional location corresponding to the determined three-dimensional location of the electrode.
6. (Original) The method of claim 3 wherein:
- the medical device includes at least one ablation electrode;
- step (e) includes determining the relative three-dimensional location of the at least one ablation electrode; and
- the method further includes the steps of:
- (f) forming a lesion using the at least one ablation electrode; and
- (g) generating a visual representation of the lesion and superimposing the visual representation on the model at a three-dimensional location corresponding to the determined three-dimensional location of the electrode.

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7. (Currently Amended) The method of claim 1 wherein the model generated in step (a) includes anatomical features known to exist in the actual region of interest, wherein the physical characteristics include anatomical features, and wherein step (c) includes deforming performing transformations on the model to correlate at least a portion of the anatomical features on the model with the determined three-dimensional locations of corresponding anatomical features in the living body.

8. (Original) The method of claim 7 wherein step (c) includes scaling the model to correlate at least a portion of the anatomical features on the model with the determined three-dimensional locations of corresponding anatomical features in the living body.

9. (Original) The method of claim 7 wherein step (c) includes orienting the model to correlate at least a portion of the anatomical features of the model with the determined three-dimensional locations of the corresponding anatomical features in the living body.

10. (Original) The method of claim 7 wherein step (c) includes performing a rigid body transformation.

11. (Original) The method of claim 10 wherein the rigid body transformation uses a procrustean algorithm.

12. (Original) The method of claim 1 wherein step (c) includes performing vector field interpolation on the model.

13. (Original) The method of claim 1 wherein the region of interest is an organ.

14. (Original) The method of claim 13 wherein the organ is a heart.

15. (Currently Amended) A method of generating a three-dimensional graphical model of an organ located within a living body, comprising the steps of

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- (a) generating a three-dimensional model of at least a portion of an organ, the model including a plurality of anatomical features corresponding to anatomical features in the organ;
- (b) obtaining the relative three-dimensional locations of known anatomical features in the organ using a reference probe positioned in the organ;
- (c) ~~deforming~~ performing transformations on the model using the determined relative three-dimensional locations of the anatomical features in the organ to approximately correlate the three-dimensional locations of the anatomical features on the model to the determined locations of corresponding anatomical features in the organ; and
- (d) graphically displaying the model.

16. (Currently Amended) The method of claim 15 further including the steps of:

- (e) obtaining the relative three-dimensional location of an additional physical characteristic in the organ using at least one probe positioned in the organ; and
- (f) ~~further deforming~~ performing another transformation on the model to approximately incorporate at least a portion of the additional physical characteristic.

17. (Original) The method of claim 16 further including repeating steps (e) and (f) multiple times for different probe locations to increase the conformity of the model to the organ.

18. (Original) The method of claim 17 wherein the repeating step includes repositioning the at least one probe multiple times within the organ.

19. (Original) The method of claim 15 further including the step of determining the relative three-dimensional location of a medical device positioned in the organ and graphically representing the medical device superimposed on the model at the determined three-dimensional location.

20. (Original) The method of claim 19 wherein the medical device is the at least one probe.

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21. (Original) The method of claim 15 wherein the reference probe includes a plurality of ultrasonic transducers thereon, and wherein:

step (b) includes the steps of using ultrasound triangulation techniques to determine the three-dimensional locations of the ultrasonic transducers, and deriving the relative three-dimensional locations of the anatomical features using the relative three-dimensional locations of the ultrasonic transducers.

22. (Currently Amended) The method of claim 21 further including the steps of:

(e) providing an additional probe having at least one ultrasonic transducer thereon;

(f) positioning the additional probe in the organ;

(g) determining the three-dimensional location of the at least one ultrasonic transducer using ultrasound triangulation techniques;

(h) deriving the relative three-dimensional locations of an additional physical characteristic in the organ using the determined three-dimensional locations of the ultrasound transducers; and

(i) ~~further deforming~~ performing another transformation on the model to approximately incorporate at least a portion of the additional physical characteristic.

23. (Currently Amended) A method of generating a three-dimensional graphical model of a heart located within a living body, comprising the steps of:

(a) generating a three-dimensional model of the heart, the model including a plurality of anatomical features corresponding to known anatomical features of hearts;

(b) obtaining the relative three-dimensional locations of known anatomical features in the heart using a reference catheter positioned in the heart;

(c) ~~deforming~~ performing transformations on the model using the determined relative three-dimensional locations of the anatomical features in the organ to approximately correlate the three-

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dimensional locations of the anatomical features on the model to the determined locations of corresponding anatomical features in the heart;

- (d) positioning an additional probe in a chamber of the heart;
- (e) obtaining the relative three-dimensional location of a physical characteristic in the chamber using the additional probe;
- (f) ~~further deforming~~ performing another transformation on the model to approximately incorporate at least a portion of the physical characteristic; and
- (g) graphically displaying the model.

24. (Original) The method of claim 23 further comprising the step of repositioning the additional probe and repeating steps (e) and (f) multiple times to increase the conformity of the model to the heart.

25. (Original) The method of claim 23 further including the steps of:

- (h) providing a medical device having at least one electrode;
- (i) positioning the medical device in the chamber; and
- (j) determining the relative three-dimensional location of the at least one electrode and graphically representing the electrode superimposed on the model at the determined three-dimensional location.

26. (Original) The method of claim 25 wherein the medical device is the at least one probe.

27. (Original) The method of claim 23 further comprising the steps of:

- (h) providing a medical device having at least one mapping electrode;
- (i) positioning the medical device in the chamber;
- (j) determining the relative three-dimensional location of the at least one mapping electrode
- (k) detecting electrical activity using the at least one mapping electrode; and

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(h) (l) generating a map of the detected electrical activity and superimposing the map on the model at a three-dimensional location corresponding to the determined three-dimensional location of the electrode.

28. (Currently Amended) The method of claim 27 wherein the medical device includes a plurality of mapping electrodes, wherein steps (j) through (h) (l) are carried out using the plurality of mapping electrodes, and wherein the map generated in step (h) (l) is an isochronal map.

29. (Currently Amended) The method of claim 27 wherein the medical device includes a plurality of mapping electrodes, wherein steps (j) through (l) are carried out using the plurality of mapping electrodes, and wherein the map generated in step (h) (l) is an isopotential map.

30. (Original) The method of claim 23 further including the steps of:

(h) providing a medical device having at least one ablation electrode;

(i) positioning the medical device in the chamber;

(j) determining the relative three-dimensional location of the at least one ablation electrode;

(k) forming a lesion using the at least one ablation electrode; and

(l) generating a visual representation of the lesion and superimposing the visual representation on the model at a three-dimensional location corresponding to the determined three-dimensional location of the electrode.

31. (Currently Amended) A system for generating a three-dimensional graphical model of a region located within a living body, comprising:

a graphical display;

display software for generating a model of a region of interest and for displaying the model on the graphical display;

a probe positionable with a region in a living body corresponding to the region of interest;

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a localization system for determining the three-dimensional location of at least a portion of the probe when the probe is positioned in a living body, and for deriving the three-dimensional location of a physical characteristic in the region of interest from the determined three-dimensional location of the probe; and

~~transformation software for deforming~~ performing a transformation on the model to at least approximately incorporate the physical characteristic at the determined three-dimensional location.

32. (Original) The system of claim 31 wherein:

the system further includes a medical device positionable in the region of interest;

the localization system is further for determining the relative three-dimensional location of the medical device when it is positioned in the region of interest in the living body; and

the display software is further for graphically representing the medical device superimposed on the model at the determined three-dimensional location.

33. (Original) The system of claim 32 wherein:

the medical device includes at least one electrode;

the localization system is further for determining the relative three-dimensional location of the electrode when it is positioned in the region of interest in the living body; and

the display software is for graphically representing the electrode superimposed on the model at the determined three-dimensional location.

34. (Original) The system of claim 32 wherein:

the medical device includes at least one mapping electrode;

the localization system is further for determining the relative three-dimensional location of the mapping electrode when it is positioned in the region of interest in the living body;

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the system further includes an electrophysiology system for receiving detected electrical activity from the mapping electrode and for generating a map of the electrical activity; and

the display software is for graphically representing the map superimposed on the model at the three-dimensional location corresponding to the three-dimensional location of the electrode.

35. (Original) The system of claim 32 wherein:

the medical device includes at least one ablation electrode;

the localization system is further for determining the relative three-dimensional location of the ablation electrode when it is positioned in the region of interest in the living body;

the system further includes an ablation system for delivering ablation energy to the ablation electrode; and

the display software is for generating a visual representation of an ablation lesion and for superimposing the visual representation of the lesion on the model at a three-dimensional location corresponding to the three-dimensional location of the electrode.

36. (Original) The system of claim 31 wherein the display software is for generating and displaying a model of an organ.

37. (Original) The system of claim 36 wherein the organ is a heart.

38. (Currently Amended) A system for generating a three-dimensional graphical model of an organ located within a living body, comprising:

a graphical display;

display software for generating a model of an organ and for displaying the model on the graphical display, the model including a plurality of anatomical features corresponding to anatomical features in the organ;

a reference probe positionable within or in proximity to an organ in a living body;

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a localization system for determining the three-dimensional location of at least a portion of the reference probe when the probe is positioned within or in proximity to the organ, and for deriving the three-dimensional locations of anatomical features in the organ from the determined three-dimensional location of the reference probe; and

~~transformation software for deforming performing transformations on~~ the model to at least approximately correlate the three-dimensional locations of the anatomical features on the model to the determined locations of corresponding anatomical features in the organ.

39. (Currently Amended) The system of claim 38 wherein:

the system further comprises an additional probe positionable within or in proximity to the organ;

the localization system is further for obtaining the relative three-dimensional location of at least a portion of the additional probe and for deriving the three-dimensional location of an additional physical characteristic of the organ from the three-dimensional location of the additional probe; and

the transformation software is further for ~~deforming performing another transformation on~~ the model to approximately incorporate at least a portion of the additional physical characteristic.

40. (Currently Amended) The system of claim 39 wherein:

the probe is moveable to multiple locations within the organ;

the localization system is further for deriving the locations of multiple physical characteristics within the organ from each of the multiple locations of the additional probe; and

the ~~transformation software~~ is further for ~~deforming performing transformations on~~ the model to approximately incorporate the multiple physical characteristics to increase the conformity between the model and the organ.

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41. (Original) The system of claim 38 wherein the organ is a heart.

42. (Original) The system of claim 41 wherein:

the system further includes a medical device positionable in the heart;

the localization system is further for determining the relative three-dimensional location of the medical device when it is positioned in the heart; and

the display software is further for graphically representing at least a portion the medical device superimposed on the model at the determined three-dimensional location.

43. (Original) The system of claim 42 wherein:

the medical device includes at least one electrode;

the localization system is further for determining the relative three-dimensional location of the at least one electrode when it is positioned in the heart; and

the display software is for graphically representing the electrode superimposed on the model at the determined three-dimensional location.

44. (Original) The system of claim 42 wherein

the medical device includes at least one mapping electrode;

the localization system is further for determining the relative three-dimensional location of the at least one mapping electrode when it is positioned in the heart;

the system further includes an electrophysiology system for receiving detected electrical activity from the mapping electrode and for generating a map of electrical activity within the heart; and

the display software is further for superimposing the map on the model at a three-dimensional location corresponding to the three-dimensional location of the electrode.

45. (Original) The system of claim 42 wherein:

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the medical device includes at least one ablation electrode;

the localization system is further for determining the relative three-dimensional location of the at least one ablation electrode when it is positioned in the heart;

the system further includes an ablation system for delivering ablation energy to the ablation electrode to create a lesion in the heart; and

the display software is further for generating a visual representation of an ablation lesion and for superimposing the visual representation on the model at a three-dimensional location corresponding to the three-dimensional location of the electrode.

46. (Original) The system of claim 44 wherein the medical device includes a plurality of mapping electrodes, wherein the electrophysiology system is for generating an isochronal map, and wherein the display software is for superimposing the map on the model.

47. (Original) The system of claim 44 wherein the medical device includes a plurality of mapping electrodes, wherein the electrophysiology system is for generating an isopotential map, and wherein the display software is for superimposing the map on the model.

48. (Currently Amended) A method of graphically displaying and dynamically correcting an image of an organ comprising the steps of:

generating a graphical model of the organ;

inserting a catheter into the body and obtaining data corresponding to the location of a physical characteristic associated with the organ;

~~deforming~~ performing a transformation on the graphical model with using the location data to increase the conformity of the model to the actual organ within the body; and

displaying the ~~deformed~~ transformed graphical model.

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49. (Currently Amended) ~~A method as recited in~~ The method of claim 48 wherein the physical characteristic is an anatomical feature.

50. (Currently Amended) ~~A method as recited in~~ The method of claim 48 wherein the physical characteristic is an interior point.

51. (Currently Amended) ~~A method as recited in~~ The method of claim 48 wherein the physical characteristic is a surface point.

52. (Currently Amended) ~~A method as recited in~~ The method of claim 48 further include the step of repositioning the catheter multiple times and repeating the obtaining, ~~deforming~~ transformation and displaying steps for each catheter position.

53. (Currently Amended) ~~A method as recited in~~ The method of claim 48 further including the step of obtaining a fluoroscopic image of the catheter and its position with respect to the organ and ~~deforming performing another transformation on~~ the graphical model using the fluoroscopic position information.

54. (Currently Amended) ~~A method as recited in~~ The method of claim 48 further including the step of obtaining input specifying the physical characteristic associated with the organ and ~~deforming performing another transformation on~~ the graphical model with using the input.

55. (Currently Amended) ~~A method as recited in~~ The method of claim 48 wherein the method further comprises the steps of positioning a plurality of ultrasonic transducers into the body, at least one of the ultrasonic transducers being on the catheter, and wherein the obtaining step includes the steps of:

causing the transducers to generate and/or receive ultrasound signals and recording the elapsed time between the generation of signals from each transmitting one of the transducers and the receipt of the signals by receiving ones of the transducers;

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determining the three-dimensional location of the catheter based on the recorded times; and
deriving the location of the physical characteristic from the determined location of the
catheter.

56. (Currently Amended) A system for graphically displaying and dynamically correcting a
model of an organ comprising:

a processor for generating a model of an organ;

a display for displaying the generated model;

a catheter for placement into the body adjacent the organ; and

means associated with the catheter for generating data related to the position of the catheter
and wherein said processor utilizes said position data to ~~deform~~ perform transformations on the
displayed model of the organ.

57. (Currently Amended) ~~A system as recited in~~ The system of claim 56 further including
means for obtaining a fluoroscopic image of the organ and the catheter further including a means for
inputting information related to the location of the catheter obtained from the fluoroscopic image
into the processor to ~~further deform~~ perform another transformation on the displayed model of the
organ.

58. (Currently Amended) ~~A system as recited in~~ The system of claim 56 wherein the system
further includes a plurality of ultrasonic transducers positionable within the living body, at least one
of the transducers being on the catheter, and wherein the means associated with the catheter
includes:

localization hardware electronically coupled to the transducers for causing the ultrasound
transducers to transmit and/or receive ultrasound signals and for measuring the elapsed time between

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transmission of ultrasound signals by transmitting transducers and receipt of the signals by receiving transducers;

processor means electronically coupled to the localization hardware for calculating the distances between the transducers using the measured elapsed time, for determining the three-dimensional location of the catheter, and for deriving the location of the organ from the three dimensional location of the catheter.

59. (Currently Amended) A system for graphically displaying and dynamically correcting a model of a region located within a living body, comprising:

a processor for generating a three-dimensional model of a region of interest;

a display for graphically displaying the generated model;

a probe for placement into the body at the region of interest; and

means associated with the probe for generating data related to the three-dimensional position of the probe and wherein said processor utilizes said position data to ~~deform~~ perform transformations ~~on~~ the model of the region of interest to alter to the shape of the model so as to increase the conformity of the model to the actual region of interest within the body.

60. (Currently Amended) A method of graphically displaying and dynamically correcting a model of a region located within a living body, comprising the steps of:

generating a three-dimensional model of a region of interest;

graphically displaying the generated model;

positioning a probe within the body at the region of interest;

generating position data related to the three-dimensional position of the probe within the body and using said position data to ~~deform~~ perform transformations on the model of the region of

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interest to alter the shape of the model so as to increase the conformity of the model to the actual region of interest within the body.